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## Scaling-up for commercial manufacturing of an allogeneic product

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Over the last years, numerous Advanced Therapy Medicinal Products (ATMP) have followed a path from academic area to industry. Still, several factors are contributing today to slowing-down of the progress of clinical trials: 1) Regulatory aspects and lack of guidelines maturity; 2) Complexity of cell therapy techniques; 3) Challenges in scaling-up of manufacturing. The main complications in scaling-up of manufacturing of cell therapy products are in a strong correlation with their nature: they are living cells and pharmaceuticals at the same time.

Since allogeneic products are on the way to commercial success, it is crucial for a manufacturer to put in place adequate bioprocessing strategies and technologies to scale up lot sizes and reduce the cost of goods (COGs) of these expensive products. In addition, the manufacturers need to focus on the choice of the primary container for the cell therapy product and aseptic fill and finish process to ensure safety and scalability.

AT-Closed Vial® Technology is an aseptic fill and finish solution, based on a ready-to-use closed vial suitable for cryopreservation of ATMP.

The AT-Closed Vial® is manufactured in ISO 5 clean room with the stopper secured in place and gamma sterilized. This container guarantees 100% of Container Closure Integrity during cryogenic storage and widely used in the area of ATMP.

All equipment types process the AT-Closed Vial® in the same way: 1) the filling is performed by a special needle piercing the stopper and dispensing the drug product in the vial; 2) the stopper is then immediately resealed by a laser and 3) a cap is snap-fitted on it. The benefits of the technology are: quick and safe process even during manual operations, safe cryopreservation, better sterility assurance, reduced COGs, low product loss, scalability to automated process.

Isolated Crystal® L1, an integrated process equipment is a brand new all-in-one scaling-up solution, combining a simple isolator with short decontamination cycle and a robotic Crystal® L1 Filler for up to 600 vials per hour.

### Biography

Olga Bukatova has built her experience in implementation of aseptic fill and finish processes in biotechnology area, mainly in ATMP.

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